MAY - 9 2011

K103611

us endoscopy

listening...and delivering solutions

510(K) EXECUTIVE SUMMARY FOR UNITED STATES ENDOSCOPY GROUP, INC'S UROLOGY MONOPOLAR SNARE

Device Description:

The Urology Monopolar Snare for tissue transection is intended to be used in the urological tract for tissue transection for histopathologic examination.

The Urology Monopolar Snare is a sterile device and consists of single lumen catheter attached to a 3-ring handle at the proximal end. The Urological Snare incorporates a braided stainless steel wire in a loop or hexagonal configuration that is attached to a stainless steel drive-wire and is extendable and retractable with respect to the catheter distal tip. The Urological snare is a Monopolar radio frequency device. The handle contains an active cord connection to make the connection to an electrosurgical generator.

The Urology Monopolar Snare is intended for single patient use only. The packaging consists of a peel pouch technology to preserve the sterile condition prior to use.

Functional Technology:

The Urology Monopolar Snare for tissue transection is intended to be used in the urological tract for tissue transection for histopathologic examination.

The only assembly required is the attachment of the radio frequency current cord to the device and to an appropriate electrosurgical generator.

When tissue transection in the urological tract is desired, the snare is used to entrap the tissue and applies radio frequency current to resect the targeted tissue and provide hemostasis. The tissue specimen is then removed per standard fluid & specimen evacuation or grasping techniques.

Intended Use:

The Urology Monopolar Snare for tissue transection is intended to be used in the urological tract for tissue transection for histopathologic examination.

Substantial Equivalence:

The device that is substantially equivalent to US Endoscopy's Urology Monopolar Snare is US Endoscopy Flexible Snare, cleared on 11-24-1992 under 510(k) Accession number K924105 and the Cook Urological Endosnare cleared on 6-07-1993 under 510(k) Accession number K923031.

Device Comparison Table

Features	**Proposed Urology Monopolar Snare**	**Flexible Snare US Endoscopy 510(k) K924105**	**Cook Medical Endosnare 510(k) 923031**
Indications for Use	The Urology Monopolar Snare for tissue transection is intended to be used in the urological tract for tissue transection for histopathologic examination.	The snare is used in flexible endoscopy to grasp, dissect and transect tissue during endoscopic procedures for histopathologic examination.	This device is intended to remove bladder tumors and coagulate the area in which the tumor was removed for patients with superficial papillary tumors of the urinary bladder.
Mode of Operation	Stainless steel cable transection via Monopolar current and mechanical means	Stainless steel cable transection via Monopolar current and mechanical means	Stainless steel wire transection via Monopolar current and mechanical means.
Sterile	Yes	Yes	Yes
Where used	Urology	Gastroenterology	Urology
Usage	Single Patient	Single Patient	Single Patient
Energy used/ delivered	Monopolar Radio Frequency current	Monopolar Radio Frequency current	Monopolar Radio Frequency current

The US Endoscopy Urology Monopolar Snare is comparable to the US Endoscopy Flexible Snare device and the Cook Urological Endosnare in intended use and mode of operation.

Technological Characteristics: The US Endoscopy Monopolar Snare operates comparably to the listed predicate device and raises no new issues of safety or effectiveness.

Performance Standards: Although no performance standards or special controls have been developed under Section 514 of the FDC Act for this device, US Endoscopy has elected to test the Urology Monopolar Snare against the standards referenced in this submission.

Performance Data: The performance data found in this submission shows that the US Endoscopy Urology Monopolar Snare performs as intended.

Conclusion: The data presented in this submission shows that the US Endoscopy Urology Monopolar Snare performs as intended and in a manner that is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

Mr. Carroll L. Martin
Regulatory Manager
US Endoscopy Group, Inc.
5976 Heisley Road
MENTOR OH 44060

MAY - 9 2011

Re: K103611
Trade/Device Name: Urology Monopolar Snare
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FDI
Dated: April 14, 2011
Received: April 15, 2011

Dear Mr. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

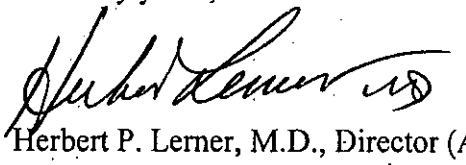
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: Urology Monopolar Snare

Indications for Use:

The Urology Monopolar Snare for tissue transection is intended to be used in the urological tract for tissue transection for histopathologic examination.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103611